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(Original Signature of Member)

109TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to provide enhanced criminal penalties for certain violations of the Act involving knowing concealment of evidence of a serious adverse drug experience, and for other purposes.

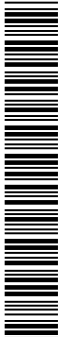
IN THE HOUSE OF REPRESENTATIVES

Mr. STARK introduced the following bill; which was referred to the Committee
on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide enhanced criminal penalties for certain violations of the Act involving knowing concealment of evidence of a serious adverse drug experience, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*



1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Pharmaceutical Re-
3 search and Manufacturers Accountability Act of 2005” or
4 the “PhRMA Act of 2005”.

5 **SEC. 2. CONCEALMENT OF SERIOUS ADVERSE DRUG EXPE-**
6 **RIENCE.**

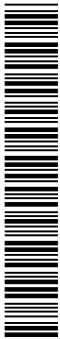
7 (a) PENALTY FOR KNOWING CONCEALMENT OF SE-
8 RIOUS ADVERSE DRUG EXPERIENCE.—Section 303 of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333)
10 is amended by adding at the end the following:

11 “(h) An individual who violates a provision of section
12 301 shall be imprisoned for a term of a minimum of 20
13 years and a maximum of life, fined not more than
14 \$2,000,000, or both, if—

15 “(1) the individual is employed as the chief ex-
16 ecutive officer or a member of the senior executive
17 management group of the manufacturer of a drug;
18 and

19 “(2) the violation involves, with respect to such
20 drug, knowing concealment by the individual of evi-
21 dence of a serious adverse drug experience (as that
22 term is defined in section 505(o)).”.

23 (b) ANNUAL ATTESTATION BY CEO REGARDING ANY
24 SERIOUS ADVERSE DRUG EXPERIENCE.—The Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
26 is amended—



1 (1) in section 505 (21 U.S.C. 355), by adding
2 at the end the following:

3 “(o) ANNUAL ATTESTATION BY CEO REGARDING
4 ANY SERIOUS ADVERSE DRUG EXPERIENCE.—

5 “(1) REQUIREMENT.—For each drug for which
6 an approval of an application filed under subsection
7 (b) or (j) is in effect, the Secretary shall require the
8 chief executive officer of the manufacturer of the
9 drug to submit a separate, written attestation on an
10 annual basis—

11 “(A) stating that the manufacturer has
12 disclosed to the Secretary all evidence of any se-
13 rious adverse drug experience related to the
14 drug; and

15 “(B) describing the process by which the
16 manufacturer ensures that such disclosure has
17 occurred.

18 “(2) DEFINITIONS.—For purposes of this sub-
19 section:

20 “(A) The term ‘evidence of any serious ad-
21 verse drug experience’ includes any evidence of
22 a serious adverse drug experience that—

23 “(i) is obtained by the manufacturer
24 involved from any source of information,
25 foreign or domestic, including any informa-



1 tion obtained from a clinical trial con-
2 ducted before or after approval of the
3 drug, from postmarketing surveillance of
4 the drug, or from a postmarketing report
5 by a physician; or

6 “(ii) is required by any provision of
7 this Act to be reported by the manufac-
8 turer to the Secretary.

9 “(B) The term ‘serious adverse drug expe-
10 rience’ means an adverse drug experience occur-
11 ring at any dose that results in—

12 “(i) death, a life-threatening adverse
13 drug experience, inpatient hospitalization,
14 prolongation of existing hospitalization, a
15 persistent or significant disability or inca-
16 pacity, or a congenital anomaly or birth
17 defect; or

18 “(ii) a medical event that, based on
19 appropriate medical judgment, may jeop-
20 ardize the patient or subject and may re-
21 quire medical or surgical intervention to
22 prevent one of the outcomes listed in
23 clause (i).



1 “(3) INITIAL ATTESTATION.—The Secretary
2 shall require that the first attestation under this
3 subsection for a drug be submitted—

4 “(A) in the case of a drug for which ap-
5 proval of an application filed under subsection
6 (b) or (j) is in effect on the date of the enact-
7 ment of this subsection, not later than 1 year
8 after such date; and

9 “(B) in the case of any other drug, not
10 later than 1 year after the the date of such ap-
11 proval for the drug.

12 “(4) FAILURE TO SUBMIT.—If the chief execu-
13 tive officer of a manufacturer of a drug for which
14 an approval of an application filed under subsection
15 (b) or (j) is in effect fails to submit a timely attesta-
16 tion for the drug as required by paragraph (1), the
17 Secretary—

18 “(A) may issue an order withdrawing ap-
19 proval of the application; and

20 “(B) shall not revoke such an order, or
21 otherwise approve or reinstate the application,
22 unless—

23 “(i) the Secretary conducts a review
24 of the drug’s safety;



1 “(ii) the Secretary determines that
2 the drug is safe for use; and

3 “(iii) the manufacturer reimburses the
4 Secretary for the costs of such review and
5 determination.

6 “(5) SUPPLEMENTAL INFORMATION.—In con-
7 ducting a review under paragraph (4)(B)(i), the Sec-
8 retary may require the manufacturer of the drug in-
9 volved to submit supplemental information on the
10 drug’s safety.”;

11 (2) in section 301 (21 U.S.C. 331), by inserting
12 at the end the following:

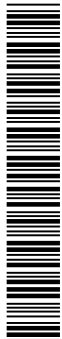
13 “(hh) The failure to submit an attestation in accord-
14 ance with section 505(o).”; and

15 (3) in section 303 (21 U.S.C. 333), as amended
16 by subsection (a), by adding at the end the fol-
17 lowing:

18 “(i)(1) A person who violates section 301(hh) by fail-
19 ing to submit an attestation in accordance with section
20 505(o) shall be fined—

21 “(A) in the case of an individual, in accordance
22 with title 18, United States Code; and

23 “(B) in the case of any other person, not more
24 than \$1,000,000.



1 “(2) Each 30-day period during which such violation
2 continues shall constitute a separate offense.”.

3 (c) DEADLINE FOR POSTMARKETING STUDIES.—

4 (1) IN GENERAL.—The Federal Food, Drug,
5 and Cosmetic Act (21 U.S.C. 301 et seq.) is
6 amended—

7 (A) in section 505 (21 U.S.C. 355), as
8 amended by subsection (b)(1), by adding at the
9 end the following:

10 “(p) DEADLINE FOR POSTMARKETING STUDIES OF
11 DRUGS.—

12 “(1) REQUIREMENT.—If the Secretary requires
13 the manufacturer or sponsor of a drug to conduct a
14 postmarketing study of the drug, the Secretary shall
15 require the manufacturer or sponsor to complete the
16 study by a specified deadline.

17 “(2) EXTENSION.—On request, the Secretary
18 may extend a deadline established under this sub-
19 section.”;

20 (B) in section 301 (21 U.S.C. 331), as
21 amended by subsection (b)(2), by inserting at
22 the end the following:

23 “(ii) The failure to complete a postmarketing study
24 by the deadline established by the Secretary for such study
25 under section 505(p).”; and



1 (C) in section 303 (21 U.S.C. 333), as
2 amended by subsections (a) and (b)(3), by add-
3 ing at the end the following:

4 “(j) A person who violates section 301(ii) by failing
5 to complete a postmarketing study for a drug by the dead-
6 line established by the Secretary for such study under sec-
7 tion 505(p) shall be fined not more than \$5,000,000. Each
8 30-day period during which such violation continues shall
9 constitute a separate offense.”.

10 (2) APPLICATION.—The amendments made by
11 this subsection apply only with respect to a drug for
12 which an application is filed under subsection (b) or
13 (j) of section 505 of the Federal Food, Drug, and
14 Cosmetic Act (21 U.S.C. 33) on or after the date of
15 the enactment of this Act.

16 (d) PROHIBITION AGAINST INDEMNIFICATION.—No
17 person shall indemnify the chief executive officer of a drug
18 manufacturer or any other individual for any fine incurred
19 under the amendments made by this Act.

